# Guidance for Industry

# Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

***DRAFT GUIDANCE***

**This guidance document is being distributed for comment purposes only.**

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For questions regarding this draft document contact LT Lysette Deshields at eDRLS@fda.hhs.gov

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**

**December 2013**
**Procedural**

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# Interim Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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*druginfo@fda.hhs.gov*
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**U.S. Department of Health and Human Services**
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# Guidance for Industry[1]

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This draft guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

## I. INTRODUCTION

This guidance is intended for outsourcing facilities that compound human drugs (outsourcing facilities). Outsourcing facilities may elect to register with FDA under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b), as added by the Drug Quality and Security Act, (DQSA). If an outsourcing facility registers, it must report to FDA information about the drugs compounded at the outsourcing facility. This guidance focuses on electronic submission of drug reporting information.

This guidance, does not establish legally enforceable responsibilities. Instead, this guidance describes the Agency's current thinking on a topic and should be viewed only as providing recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in this guidance means that something is suggested or recommended, but not required.

## II. BACKGROUND

### A. Drug Quality and Security Act

The DQSA adds new section 503B to the FD&C Act. Under section 503B(b), a compounder may elect to become an outsourcing facility by registering with FDA. Upon initially registering as an outsourcing facility, and twice each year (once in June and once in December), an outsourcer that registers with FDA must submit to the Agency a report identifying the drugs compounded by the facility during the previous 6-month period. For each identified drug, the outsourcing facility must provide certain information listed in section 503B(b).

[1] This guidance was prepared by the Office of Compliance, Center for Drug Evaluation and Research at the Food and Drug Administration.

An outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355) and the requirement to label products with adequate directions for use in section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) by meeting the requirements described in the rest of section 503B. Outsourcing facilities will be inspected by FDA and must comply with other provisions of the FD&C Act, such as current good manufacturing practice (cGMP) requirements. Information about these requirements will be provided separately at a later date.

### B. Scope of This Guidance

This guidance addresses the provisions in the DQSA regarding the drug reporting requirements for registered outsourcing facilities. A separate guidance provides instructions on how outsourcing facilities should register with FDA.[2] This guidance provides instructions for interim reporting until FDA can modify its electronic submission system to accept the electronic reports for drugs compounded by outsourcing facilities. When FDA has modified its current electronic system, we will issue a new outsourcing facility product reporting guidance describing the updated format for long-term use.

## III. SUBMISSION OF PRODUCT REPORTING

### A. Who Should Report and What to Report

Under section 503B of the FD&C Act, upon initial registration as an outsourcing facility under section 503B and twice each year (once in June and once in December), each registrant must submit a product report to FDA. This report must identify all drugs compounded by the outsourcing facility during the previous 6-month period and provide the following information for each drug:

- The active ingredient and strength of active ingredient per unit;
- The source of the active ingredient (bulk or finished drug);
- The National Drug Code (NDC) number of the source drug or bulk active ingredient, if available;
- The dosage form and route of administration;
- The package description;
- The number of individual units produced; and
- The NDC number of the final product, if assigned.

### B. When to Report

[2] See Guidance for Industry: Registration for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act, available at: http://www.fda.gov/forindustry/industrynoticesandguidancedocuments/default.htm.

Registered outsourcing facilities must report upon initial registration under section 503B of the FD&C Act, and twice each year (once in June and once in December). FDA encourages companies wishing to compound as outsourcing facilities to register with FDA immediately. If a facility registers before June 2, 2014, FDA does not intend to immediately enforce the requirement to report product information at the time of initial registration, as long as the facility submits its report within 2 months after the date of that initial registration.

### C. How to Report

Section 503B(b)(3) of the FD&C Act requires outsourcing facilities to submit drug reporting information by electronic means unless FDA grants a request for a waiver of such requirement "because use of electronic means is not reasonable for the person requesting the waiver."

Because FDA's electronic submission systems are not currently equipped to handle electronic drug reporting from outsourcing facilities in Structured Product Labeling (SPL) format, outsourcing facilities should submit reporting data to the Agency in an Excel spreadsheet, via an email attachment. Product reporting can be submitted to edrls@fda.hhs.gov. When the Agency has modified its electronic submission system to allow outsourcers to submit information electronically through an SPL file, FDA intends to issue a draft guidance describing the updated format for long-term use. When such guidance is in final form, it will specify the form of reporting that outsourcing facilities are to follow. A sample Excel spreadsheet for an interim outsourcing facility product submission can be found at Appendix 1.

FDA does not anticipate many instances in which electronic submission of reporting information will not be reasonable for the outsourcing facility requesting a waiver. However, if a waiver is granted, the Agency will also give instructions on how to submit the required reporting information. To apply for a waiver from the requirement to electronically submit drug reporting information, please provide a written request with a complete explanation of why the use of electronic means is not reasonable to:

Drug Registration and Listing System Team
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

or

Email: edrls@fda.hhs.gov

## APPENDIX 1: SAMPLE INTERIM PRODUCT REPORTING SUBMISSION

**Interim Product Reporting for Human Drug Compounding Outsourcing Facilities**

**Outsourcing Facility Information**

| Facility Name | UFI | Contact Name | Contact Phone | Contact Email |
|---|---|---|---|---|
| | | | | |

**Product Information**

| Product Name | Product NDC | Active Ingredient Name | Strength of Active Ingredient/ Unit | Dosage Form | Route of Administration | Package Description | # of Units |
|---|---|---|---|---|---|---|---|
| | | | | | | | |

**Source NDC**

| NDC | Bulk or Finished |
|---|---|
| | |